

Appl. No. : **10/009,792**
Filed : **December 13, 2001**

REMARKS

This is in response to the Final Official Action mailed May 20, 2005. Applicants gratefully acknowledge that Claims 1, 2, and 7-10 have been allowed. Applicants also gratefully acknowledge the removal of several grounds of rejection set forth in the previous Office Action. Claims 3-6 and 11-13 remain presented for examination. No new matter has been added by this amendment.

A certified copy of the priority document, Korean Application No. 10-2000-0017052 was mailed to the USPTO on May 13, 2005. Additionally, a courtesy copy of the priority document was faxed to the Examiner on May 17, 2005, at Fax No. (571) 273-0854.

The Examiner maintained the previous rejection of claim 13 under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 13 has now been amended to add the language “the nucleotide sequence of” after “1-84 of”, as suggested by the Examiner in a teleconference held on April 25, 2005.

The Examiner rejected claim 3 and those claims dependent therefrom under 35 U.S.C. § 112, first paragraph, as allegedly containing new subject matter. Specifically, the Examiner alleged that the amended term “lacking its native signal sequence” is not supported by the specification as filed.

Applicants note that the requirements of the first paragraph of 35 U.S.C. §112 are satisfied by the specification as filed with respect to the term “lacking its native signal sequence.” In particular, Applicants note that as decided in *Ex parte Parks* (Bd Pat App & Inter, 30 U.S.P.Q. 2d 1234 (1993)), the requirements of the first paragraph of 35 U.S.C. §112 are satisfied if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that Applicants had possession of the claimed subject matter, even if a particular concept was not literally stated in the originally filed application. In particular, in *Parks*, the Board of Patent Appeals and Interferences found that the written description requirement was satisfied with respect to a claim limitation specifying that the claimed process was performed “in the absence of a catalyst” despite the fact that those exact words did not appear in the specification as filed because the originally filed specification conveyed to those skilled in the art that applicant had possession of the concept of performing the method in the absence of a catalyst.

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The phrase “lacking its native” was added to claim 3 of the instant invention to avoid confusion with the added signal sequence (the *Bacillus sp.* endoxylanase signal sequence) that is cited in another element of the claim. The specification at page 10, lines 12-26 describes clearly how the hG-CSF sequence of the claimed invention does not have its own, original, native, signal sequence, but has now been modified to contain a signal sequence of another organism. One of skill in the art would fully understand this upon reading the specification. Applicants believe that Examiner’s suggested amendment to use the phrase “with its signal sequence removed” would result in additional confusion, since it may appear that the native signal sequence of the hG-CSF would need to be specifically removed by the practitioner (rather than, for example, being obtained from another source with the sequence absent already) in order for the claim to be valid. In other words, by the term “lacking its native signal sequence” Applicants are simply putting in the result of the step of removing the native signal sequence of hG-CSF (page 10, lines 12-26), in order to create a clear representation of the claimed vector.

The Examiner’s proposed language would be confusing because, as shown in Figure 4 and Example 2 (page 10, lines 12-26), the signal sequence does not have to be physically “removed” to be “lacking.” For example, PCR methods, using specifically designed primers, can be used to prepare hG-CSF sequence that lacks its original, native sequence. The top portion of Figure 4 shows this clearly, where a forward and reverse primer are designed to isolate hG-CSF without its signal sequence. Example 2 shows a detailed example of how one of skill in the art could prepare the hG-CSF sequence lacking its own, native, original signal sequence.

Applicants have endeavored to address all of the Examiner’s concerns as expressed in the outstanding Office Action. In light of the above Amendments and Remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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